4. PROGRAM REGULATIONS

423.401: Introduction

130 CMR 423.000 establishes the requirements for the provision and reimbursement of freestanding ambulatory surgery center services under the Medical Assistance Program. The Division pays for freestanding ambulatory surgery center services that are medically necessary and appropriately provided in the most cost-effective setting; that is, the total cost of the service (for example, the rate of payment for the corresponding payment group including directly related ancillaries, plus the cost of prosthetic devices or implants) does not exceed the cost to Medicaid of providing that same service in any other medically appropriate setting, as determined by the Division or its agent. The quality of the services delivered to Medical Assistance recipients must meet professionally recognized standards of care.

423.402: Definitions

The following terms used in 130 CMR 423.000 shall have the meanings given in this section, unless the context clearly requires a different meaning.

The Division ✍ the Massachusetts Division of Medical Assistance.

Emergency ✍ the unexpected onset of symptoms or a condition requiring immediate medical or surgical care that is beyond the treatment capabilities of the freestanding ambulatory surgery center.

Freestanding Ambulatory Surgery Center ✍ a facility, geographically independent of any other health-care facility, that operates autonomously and functions exclusively for the purpose of providing outpatient same-day surgical, diagnostic, and medical services requiring a dedicated operating room and a postoperative recovery room. These surgical, diagnostic, and medical services provide diagnosis or treatment through operative procedures requiring general, local, or regional anesthesia, and must be furnished to patients who do not require hospitalization or overnight services upon completion of the procedure, but who require constant medical supervision for a limited amount of time following the conclusion of the procedure. A freestanding ambulatory surgery center does not include individual or group-practice offices of private physicians, dentists, or podiatrists, and does not include any clinic devoted exclusively to the performance of any single surgical procedure or specialty. A freestanding ambulatory surgery center must be an entity subject to a determination of need by the Massachusetts Department of Public Health pursuant to M.G.L. c. 111, s. 25C. These centers are referred to as surgical centers in 130 CMR 423.000.

Individual Consideration ✍ a designation given to a claim that will receive individual consideration (I.C.) to determine payment where a fee could not be established.

Operative Report – a report that states the operation performed, the name of the recipient, the date of the operation, the preoperative diagnosis, the postoperative diagnosis, the names of the surgeon and his or her assistants, and the technical procedures performed.

423.403: Eligible Recipients

The Division will pay for surgical center services provided to Medical Assistance recipients (categories of assistance 0, 1, 2, 3, 5, 6, 7, and 8), subject to the restrictions and limitations described in 130 CMR 423.000. For information on reimbursable services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program (category of assistance 4), see 130 CMR 450.111. For information on the Division's Managed Care Program and its program requirements, see 130 CMR 450.116 through 450.119.

423.404: Provider Eligibility

Payment for the services described in 130 CMR 423.000 will be made only to in-state and out-of-state surgical centers participating in the Medical Assistance Program on the date of service. The Division has established the provider eligibility requirements listed below for in-state and out-of-state providers. Providers must meet all of these requirements to participate in the Medical Assistance Program as a surgical center.

(A) Procedures for Hospitalization. An in-state or out-of-state surgical center must have established procedures to ensure recipient transfer to a hospital in the event an emergency occurs that requires treatment beyond the capabilities of the surgical center. Either the surgical center must have a written transfer agreement with a hospital, or all the dentists, physicians, and podiatrists with surgical privileges at the surgical center must have admitting privileges at the hospital. The hospital must be a Massachusetts Medicaid-participating provider, and must be licensed to operate as a hospital in accordance with the regulations of the Massachusetts Department of Public Health at 105 CMR 130.000 or with its own state's licensing agency.

(B) In-State Providers. To participate in the Massachusetts Medical Assistance Program, an in-state surgical center must:

(1) obtain a Massachusetts Medical Assistance Program provider number from the Division of Medical Assistance;

(2) operate under a clinic license issued by the Massachusetts Department of Public Health, in accordance with regulations at 105 CMR 140.000;

(3) participate in the Medicare program as an ambulatory surgery center;
(4) be accredited by a national accrediting body for ambulatory surgery centers;
(5) provide a minimum of three surgical specialties, with no single surgical specialty constituting more than 40 percent or less than 12 percent of the total volume of procedures performed at the surgical center; and
(6) have a minimum of two dedicated operating rooms.

(C) Out-of-State Providers.
(1) To participate in the Massachusetts Medical Assistance Program, an out-of-state surgical center must:
(a) obtain a Massachusetts Medical Assistance Program provider number from the Division of Medical Assistance;
(b) participate in its own state's Medical Assistance program;
(c) operate as a provider of surgical center services as authorized by the governing or licensing agency in its state;
(d) participate in the Medicare program as an ambulatory surgery center;
(e) be accredited by a national accrediting body for ambulatory surgery centers;
(f) provide a minimum of three surgical specialties, with no single surgical specialty constituting more than 40 percent or less than 12 percent of the total volume of procedures performed at the surgical center; and
(g) have a minimum of two dedicated operating rooms.
(2) Out-of-state surgical center services provided to an eligible Massachusetts Medical Assistance recipient are reimbursable only when:
(a) the surgical services are provided to a recipient who resides in a community located within a 50-mile radius of the Massachusetts border at Connecticut, Maine, New Hampshire, New York, Rhode Island, or Vermont and for whom the out-of-state freestanding ambulatory surgery center is nearer than a facility in Massachusetts providing equivalent surgical services; or
(b) an out-of-state surgical center that is more than 50 miles from the Massachusetts border obtains prior authorization from the Division to provide any surgical center services to a recipient. This prior authorization is required in addition to the prior-authorization requirements found at 130 CMR 423.406. All requests for prior authorization must be submitted in accordance with the instructions found in Subchapter 5 of the Freestanding Ambulatory Surgery Center Manual. No payment will be made for such services unless prior authorization has been obtained from the Division before the delivery of service. The Division will not grant retroactive prior-authorization requests.

423.405: Reimbursement

Reimbursement for a surgical procedure performed at a surgical center consists of two components the facility component and the professional component.

(A) Facility Component. The facility component is an all-inclusive fee that reimburses the surgical center for rent, equipment, utilities, supplies, salaries and benefits for administrative and technical staff, and other overhead expenses.

(1) This fee includes payment for:

(a) surgical center facilities and equipment;

(b) nursing services, technician services, and other related services;

(c) drugs, biologicals, surgical dressings, supplies, splints, casts, appliances, and equipment directly related to the provision of the surgical procedures;

(d) administrative, recordkeeping, and housekeeping items and services;

(e) materials for anesthesia;

(f) blood;

(g) urinalysis and blood hemoglobin and hematocrit; and

(h) diagnostic or therapeutic services related to the provision of the surgical procedure.

(2) Payment for both in-state and out-of-state surgical center services will be made in accordance with the rate or rates of payment established for surgical centers by the Massachusetts Rate Setting Commission at 114.3 CMR 44.00. Surgical procedures are classified into payment groups. All procedures within a payment group are assigned the same rate.

(a) Multiple Procedures. If more than one reimbursable surgical procedure requiring an unrelated operative incision is provided in a single operative session, the full maximum fee is 100 percent for the operative procedure in the highest payment group and a percentage of the payment-group rate, as determined by the Massachusetts Rate Setting Commission, for each additional reimbursable procedure.

(b) Bilateral Procedures. If a reimbursable surgical procedure provided in a single operative session is performed bilaterally, the full maximum fee is 150 percent of the payment-group rate for the operative procedure.

(c) Cancelled Procedures. The Division will not pay for a surgical procedure that is cancelled or postponed, for any reason, before the procedure is initiated.

(d) Terminated Procedures.

(i) The Division will determine payment on an individual-consideration (I.C.) basis for procedures that have been terminated after the procedure has been initiated. Appropriate payment for an I.C. service will be determined by the Division from the operative report of services furnished. Reimbursement of prosthetic devices depends on the preparation of the device. The preparation of the prosthetic device must require distinct preliminary measures (for example, immersion in an antibiotic solution) and does not include the action of opening a sterile implant onto the surgical field or instrument table.

(ii) The facility must use the service code in Subchapter 6 of the Freestanding Ambulatory Surgery Center Manual designated for terminated procedures. An operative report, including the operative summary, nursing notes, and anesthesia record, must accompany the claim. If a report is not submitted, no payment will be made. If, after review of the operative summary, nursing notes, and anesthesia record, the Division determines that there should be reimbursement for the prosthetic device, then this reimbursement will be included in the reimbursement for the terminated procedure.

(B) Professional Component. Payment for professional services furnished by a dentist, podiatrist, or physician in a surgical center will be made in accordance with the Division's regulations at 130 CMR 420.000, 424.000, and 433.000, respectively. All professional services must be furnished by a provider participating in the Medical Assistance Program.

423.406: Prior Authorization

(A) The Division requires the surgeon to obtain prior authorization for services that are designated "P.A." in the service descriptions listed in Subchapter 6 of the Freestanding Ambulatory Surgery Center Manual. No payment will be made for such services unless prior authorization has been obtained from the Division before the delivery of service. The Division will not grant retroactive prior-authorization requests.

(B) Prior authorization determines only the medical necessity of the authorized service and does not establish or waive any other prerequisites for payment such as, but not limited to, recipient eligibility or resort to health insurance payment.

(C) Division regulations regarding prior-authorization requirements may be found in the individual program regulations for dentists, podiatrists, and physicians at 130 CMR 420.000, 424.000, and 433.000, respectively.

(130 CMR 423.407 through 423.412 Reserved)

423.413: Recordkeeping Requirements

Surgical centers must maintain a medical-record system promoting quality and confidential patient care in accordance with Massachusetts Department of Public Health regulations at 105 CMR 140.000. This system must collect and retain data in a comprehensive and efficient manner and permit the prompt retrieval of information. Accurate and complete medical records must be maintained for each recipient receiving surgical services from the surgical center. The data maintained in the recipient's medical record must also be sufficient to justify any further diagnostic procedures, treatments, recommendations for return visits, and referrals. The medical record must be clear and legible, and readily accessible to health care practitioners and the Division. The medical record must be maintained by the surgical center for six years.

(A) Documentation. Payment for any service reimbursable under the Medical Assistance Program is conditioned upon its full and complete documentation in the recipient's medical record. Payment for maintaining the recipient's medical record is included in the fee for the facility component. Each medical record must contain sufficient information to fully document the nature, extent, quality, and necessity of the care furnished to the recipient for each date of service claimed for payment. If the information in the recipient's record is not sufficient to document the service for which payment is claimed by the provider, the Division will not pay for the service or, if payment has been made, may consider such payment to be an overpayment subject to recovery as defined in the Division's administrative and billing regulations in 130 CMR 450.000. The medical record requirements in 130 CMR 423.000 shall constitute the standard against which the adequacy of records shall be measured, as set forth in 130 CMR 450.000.

(B) Components. The medical record must include the following:

(1) patient identification, including name, date of birth, and Medical Assistance recipient identification number;
(2) medical history and dental history, as appropriate;
(3) findings of physical examination and preoperative diagnosis;
(4) results of any preoperative diagnostic studies (entered before surgery) if ordered, including laboratory and radiologic reports. These results include dated and mounted X rays, if applicable;
(5) operative record documenting clinical findings, techniques of the operation, intraoperative medications administered, and type of surgical procedure;
(6) pathologist's reports on tissue removed in surgery, except those exempted by the governing body;
(7) date of surgery;
(8) surgeon's name, address, and telephone number;
(9) allergies and adverse drug reactions;
(10) anesthesia record describing anesthetic agents used, dosages administered, and documentation of start and end times of general or intravenous anesthesia;
(11) nursing notes (preoperative, intraoperative, and postoperative, including documentation of any medical goods or supplies dispensed);
(12) patient's surgical consent, with documentation of it as properly executed informed consent;

(13) postoperative diagnosis;
(14) discharge summary, including recommendations and referrals for additional treatment or consultations, when applicable; and
(15) records pertaining to requests for laboratory, radiologic, and/or pathology information requested in relation to the surgical procedure.

(C) Clinical Laboratory and Radiology Services. For clinical laboratory services and radiologic services, additional information must be maintained in the recipient's medical record in relation to the reimbursable surgical procedure, as well as a record of each specimen and laboratory test result for at least six years from the date on which the results were reported to the prescriber. This record must include the following components:

(1) name and any other means of identification of the patient from whom the specimen was taken, including date of birth and Medical Assistance recipient identification number;
(2) site from which the specimen was obtained;
(3) name of the person who obtained the specimen;
(4) name of the person who ordered the laboratory test;
(5) name of the person who ordered the radiologic service;
(6) authorized requisition for the test;
(7) name and address of the surgical center where the specimen was obtained;
(8) date on which the specimen was collected by the prescriber or laboratory;
(9) date on which the specimen was received in the laboratory;
(10) condition of unsatisfactory specimens when received (for example, broken, leaked, hemolyzed, turbid, or insufficient sample size);
(11) date on which the test was performed;
(12) test name and the results of the test, or the cross-reference to results and the date of reporting;
(13) name and address of the person performing the examination of the specimen; and
(14) if applicable, the name and address of a second independent laboratory consulted to examine the specimen, as well as documentation stating the necessity for further examination.

(D) Pharmacy Services. Surgical center pharmacies must maintain, for six years, a record for each recipient of the drug and amount dispensed, the date, and the original prescription. Verbal orders for the administration of all drugs and biologicals must be followed by a written order signed by the prescriber at the completion of the surgical procedure.

423.414: Reimbursable Surgical Procedures

The Division will pay surgical centers for those services listed in Subchapter 6 of the Freestanding Ambulatory Surgery Center Manual (see 130 CMR 423.401 for further requirements). All prosthetic devices, except intraocular lenses, whether implanted, inserted, or otherwise related to procedures on the current list of reimbursable surgical procedures, are reimbursed separately from the surgical center facility component. The above notwithstanding, providers must comply with the requirements specified in 130 CMR 423.401, which state that reimbursement is provided only for services that are medically necessary and furnished in the least costly medically appropriate setting.

423.415: Service Limitations

(A) The Division will not pay a surgical center for experimental, unproven, or otherwise medically unnecessary procedures or treatments performed at the center, specifically including, but not limited to, sex-reassignment surgery, thyroid cartilage reduction, and any other related surgeries and treatment, including pre- and post-sex-reassignment surgery hormone therapy. Notwithstanding the preceding sentence, the Division will continue to pay for post-sex-reassignment surgery hormone therapy for which it had been paying immediately prior to May 15, 1993.

(B) The Division will pay only for podiatry services that are certified to be necessary for the life and safety of the recipient. The Division will reimburse for podiatry services as long as the podiatrist's claim has attached to it a written certification on letterhead from the recipient's primary care physician that attests that such services are medically necessary for the life and safety of the recipient and that contains a substantiating medical explanation. A surgical center must submit a photocopy of this written certification obtained by the podiatrist from the primary care clinician and attach it to the surgical center's claim when billing the Division for services.

(C) The Division will not pay a surgical center for the treatment of male or female infertility (including, but not limited to, laboratory tests, drugs, and procedures associated with such treatment).

423.416: Sterilization Services: Introduction

(A) Eligible Recipients. Female Medical Assistance recipients in categories of assistance 0, 1, 2, 3, 5, 6, 7, and 8 are eligible for sterilization services as described in 130 CMR 423.416 through 423.418. For information on reimbursable services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program (category of assistance 4), see 130 CMR 450.111.

(B) Definitions. The following definitions apply to sterilization services:

(1) Sterilization ✍ any medical procedure, treatment, or operation that renders an individual permanently incapable of reproducing. A sterilization is "nontherapeutic" when the individual has chosen sterilization as a permanent method of contraception. A sterilization is "therapeutic" when it occurs as a necessary part of the treatment of an existing illness or injury or is medically indicated and performed in conjunction with surgery upon the genito-urinary tract.

(2) Mentally Incompetent Individual ✍ an individual who has been declared mentally incompetent by a federal, state, or local court of competent jurisdiction for any purpose, unless the individual has been declared competent for purposes that include the ability to consent to sterilization.

(3) Institutionalized Individual ✍ an individual who is:

(a) involuntarily confined or detained, under a civil or criminal statute in a correctional or rehabilitative facility, including a psychiatric hospital or other facility for the care and treatment of mental illness; or

(b) confined, under a voluntary commitment, in a psychiatric hospital or other facility for the care and treatment of mental illness.

(C) Reimbursable Services. The Division will not pay a freestanding ambulatory surgery center for sterilization services to a male recipient. The Division will pay for sterilization services provided to a female recipient only if all of the following conditions are met.

(1) The recipient has voluntarily given informed consent for the sterilization procedure in the manner and at the time described in 130 CMR 423.417, and such consent is documented in the manner described in 130 CMR 423.418.

(2) The recipient is at least 18 years old at the time consent is obtained.

(3) The recipient is not mentally incompetent or institutionalized.

(4) The sterilization is performed by a licensed physician.

(D) Assurance of Recipient Rights. No provider shall use any form of coercion in the provision of sterilization services. Neither the Division nor any provider, nor any agent or employee of a provider, shall mislead any recipient into believing that a decision to have or not to have a sterilization will adversely affect the recipient's entitlement to benefits or services for which the recipient would otherwise be eligible. The Division has strict requirements for confidentiality of recipient records for sterilization services as well as for all other medical services reimbursable under the Medical Assistance Program.

(E) Retroactive Eligibility. The Division will not pay for a sterilization performed during the period of a recipient's retroactive eligibility unless all conditions for payment listed in 130 CMR 423.416(C) are met.

423.417: Sterilization Services: Informed Consent

A recipient's consent for sterilization will be considered informed and voluntary only if such consent is obtained in accordance with the requirements specified in 130 CMR 423.417(A) and (B).

(A) Informed Consent Requirements.

(1) The person who obtains consent (a physician, nurse, or counselor, for example) must orally provide all of the following information and advice to the recipient requesting sterilization:

(a) advice that the recipient is free to withhold or withdraw consent for the procedure at any time before the sterilization without affecting the right to future care or treatment and without loss of any federal- or state-funded program benefits to which the recipient otherwise might be entitled;

(b) a description of available alternative methods of family planning and birth control;

(c) advice that the sterilization procedure is considered irreversible;

(d) a thorough explanation of the specific sterilization procedure to be performed;

(e) a full description of the discomforts and risks that may accompany or follow the procedure, including an explanation of the type and possible effects of any anesthetic to be used;

(f) a full description of the benefits or advantages that may be expected as a result of the sterilization; and

(g) advice that the sterilization will not be performed for at least 30 days, except under the circumstances specified in 130 CMR 423.417(B)(1).

(2) The person who obtains consent must also:

(a) offer to answer any questions the recipient may have concerning the sterilization procedure;

(b) give the recipient a copy of the consent form;

(c) make suitable arrangements to ensure that the information and advice required by 130 CMR 423.417(A)(1) are effectively communicated to any recipient who is blind, deaf, or otherwise handicapped;

(d) provide an interpreter if the recipient does not understand the language used on the consent form or the language used by the person obtaining consent; and

(e) allow the recipient to have a witness of the recipient's choice present when consent is obtained.

(B) When Informed Consent Must Be Obtained.

(1) A recipient's consent for sterilization will be considered informed and voluntary only if such consent is obtained at least 30 days, but not more than 180 days, before the date of the sterilization procedure, except in the case of premature delivery or emergency abdominal surgery. A recipient may not be sterilized at the time of a premature delivery or emergency abdominal surgery unless at least 72 hours have passed since the recipient gave informed consent for the sterilization in the manner specified in 130 CMR 423.417(A). In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

(2) A recipient's consent for sterilization will not be considered informed or voluntary if such consent is obtained or given while the recipient requesting sterilization is:

(a) in labor or childbirth;

(b) seeking to obtain or obtaining an abortion; or

(c) under the influence of alcohol or other substances that affect the individual's state of awareness.

(3) Shortly before the performance of the sterilization procedure, the physician performing the procedure must orally inform the recipient of all of the information and advice specified in 130 CMR 423.417(A)(1).

423.418: Sterilization Services: Consent Form Requirements

Informed consent for sterilization must be documented by the completion of the Division's Consent for Sterilization form in accordance with the following requirements. (Instructions for obtaining the Consent for Sterilization forms are located in Subchapter 5 of the Freestanding Ambulatory Surgery Center Manual.)

(A) Required Consent Form.

(1) One of the following Consent for Sterilization forms must be used:

(a) CS-18 for recipients aged 18 through 20; or

(b) CS-21 for recipients aged 21 and older.

(2) Under no circumstances will the Division accept any other consent for sterilization form.

(B) Required Signatures. The recipient, the interpreter (if one was required), and the person who obtained the consent for sterilization must all sign and date the Consent for Sterilization form (CS-18 or CS-21) at the time of consent. After performing the sterilization procedure, the physician must sign and date the form.

(C) Required Submission and Distribution of the Consent Form. The Consent for Sterilization form (CS-18 or CS-21) must be completed and distributed as follows:

(1) the original must be given to the recipient at the time of consent;

(2) a copy must be included in the recipient's permanent medical record at the site where the sterilization is performed; and

(3) all providers must attach a copy of the completed Consent for Sterilization form (CS-18 or CS-21) to each claim made to the Division for sterilization services. When more than one provider is billing the Division (for example, the physician and the freestanding ambulatory surgery center), each provider must submit a copy of the completed consent form.

423.419: Abortion Services

(A) Abortions may be performed in a surgical center in accordance with M.G.L. c. 112, s. 12I through 12N, inserted by Chapter 706 of the Acts of 1974, and with license rules and regulations of the Massachusetts Department of Public Health.

(B) A surgeon must certify that the abortion is medically necessary by completion of the Certification for Payable Abortion (CPA-2) form. The surgeon must comply with the Division's regulations at 130 CMR 433.000.

(C) All surgical centers must attach a completed CPA-2 form to each claim form submitted to the Division for a payable abortion. (Instructions for obtaining the CPA-2 form can be found in Subchapter 5 of the Freestanding Ambulatory Surgery Center Manual.) The surgical center must attach a photocopy of the completed CPA-2 form with each claim made to the Division for a payable abortion. Service codes requiring a CPA-2 form are indicated in Subchapter 6 of the Freestanding Ambulatory Surgery Center Manual.

REGULATORY AUTHORITY

130 CMR 423.000: M.G.L. c. 118E, ss 7 and 12.

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